

## Appendix A

### Available Measured Data

This appendix contains the robust summaries of the available data. Reference 9 was not summarised, because this reference consisted of a review containing summaries only.

The reports have been evaluated and assessed according to the Klimisch criteria (Klimisch et al., 1997). The following criteria can be distinguished, based on reliability, relevance and adequacy of the data:

- 1 = Reliable without restrictions,
- 2 = Reliable with restrictions,
- 3 = Not reliable,
- 4 = Not adequate.

### List of Abbreviations

a	Absolute to body weight
-	Absent
+	Present
a.i.	Active ingredient
BOD	Biochemical Oxygen Demand
BOD <sub>5</sub>	Biochemical Oxygen Demand on day 5
BUN	Blood Urea Nitrogen
COD	Chemical Oxygen Demand
d	Decrease
dc	Decrease (significant)
DOC	Dissolved Organic Carbon
F	Female
i	Increase
ic	Increase (significant)
M	Male
r	Relative to body weight
TS	Test Substance
WBC	White Blood Cells
x	yes

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**Physicochemical Properties**

<b>Title</b>	Statement on the determination of the dissociation constant(s) of Lathanol LAL powder in water.
<b>Date of report</b>	June 13, 2003.
<b>GLP</b>	Yes.
<b>Reference</b>	10.
<b>Test substance</b>	CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.
<b>Guideline</b>	OECD 112
<b>Remarks</b>	For the sulphonate group of Lathanol LAL powder a $pK_a$ of $-0.51$ was calculated with Pkalc version 5.0. Since this value is not within the range 2-11 the dissociation constant could not be determined experimentally.
<b>Conclusions</b>	$pK_a = -0.5$ .
<b>Rev. note</b>	-
<b>Klimisch criterium</b>	1

<b>Title</b>	Final report on the safety assessment of sodium lauryl sulfoacetate.
<b>Date of report</b>	1987.
<b>GLP</b>	No.
<b>Reference</b>	9.
<b>Test substance</b>	CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.
<b>Guideline</b>	Not indicated.
<b>Remarks</b>	Specific gravity = 0.55. Water solubility = 10, 000 mg/L at 25 °C. The pH of a 0.25% solution is 6.9-7.1.
<b>Rev. note</b>	-
<b>Klimisch criterium</b>	2

<b>Title</b>	EPISUITE v.3.10
<b>Date of report</b>	-
<b>GLP</b>	Not applicable.
<b>Reference</b>	18.
<b>Test substance</b>	CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.
<b>Guideline</b>	Not applicable.
<b>Remarks</b>	Melting point: 271 °C. Boiling point: 425 °C. Vapor pressure: $3.0E-14$ hPa at 25 °C. Partition coefficient o/w: 2.66. Water solubility: 3.83 mg/L at 25 °C.
<b>Rev. note</b>	Calculated.
<b>Klimisch criterium</b>	2

**Environmental Fate**

<b>Title</b>	Final report on the safety assessment of sodium lauryl sulfoacetate.
<b>Date of report</b>	1987.
<b>GLP</b>	No.
<b>Reference</b>	9.
<b>Test</b>	CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.

**substance**  
**Guideline** Not indicated.  
**Remarks** The test substance is stable in weakly acidic and weakly alkaline solutions in a pH range of 5.0-8.5.  
**Rev. note** -  
**Klimisch** 4  
**criterion**

**Title** EPISUITE v.3.10  
**Date of report** -  
**GLP** Not applicable.  
**Reference** 18.  
**Test substance** CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.

**Guideline** Not applicable.  
**Remarks** **Photodegradation (calculated):**  
 AOP Program (v1.90) Results:

=====  
 SMILES : S(=O)(=O)(O[Na])CC(=O)OCCCCCCCCCCCCC  
 CHEM : Acetic acid, sulfo-, 1-dodecyl ester, sodium salt  
 MOL FOR: C14 H27 O5 S1 Na1  
 MOL WT : 330.42

----- SUMMARY (AOP v1.90): HYDROXYL RADICALS -----

\*\*Hydrogen Abstraction = 16.1612 E-12 cm3/molecule-sec  
 Reaction with N, S and -OH = 0.0000 E-12 cm3/molecule-sec  
 Addition to Triple Bonds = 0.0000 E-12 cm3/molecule-sec  
 Addition to Olefinic Bonds = 0.0000 E-12 cm3/molecule-sec  
 Addition to Aromatic Rings = 0.0000 E-12 cm3/molecule-sec  
 Addition to Fused Rings = 0.0000 E-12 cm3/molecule-sec

OVERALL OH Rate Constant = 16.1612 E-12 cm3/molecule-sec

HALF-LIFE = 0.662 Days (12-hr day; 1.5E6 OH/cm3)

HALF-LIFE = 7.942 Hrs

..... \*\* Designates Estimation(s) Using ASSUMED Value(s)

----- SUMMARY (AOP v1.90): OZONE REACTION -----

\*\*\*\*\* NO OZONE REACTION ESTIMATION \*\*\*\*\*  
 (ONLY Olefins and Acetylenes are Estimated)

**Distribution (calculated):****Level III Fugacity Model (Full-Output):**

=====

Chem Name : Acetic acid, sulfo-, 1-dodecyl ester, sodium salt  
 Molecular Wt: 330.42  
 Henry's LC : 6.79e-010 atm-m3/mole (Henrywin program)  
 Vapor Press : 3.02e-014 mm Hg (Mppbpwin program)  
 Liquid VP : 8.26e-012 mm Hg (super-cooled)  
 Melting Pt : 271 deg C (Mppbpwin program)  
 Log Kow : 2.66 (Kowwin program)  
 Soil Koc : 187 (calc by model)

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	8.25e-006	15.9	0
Water	99.3	360	1000
Soil	0.000113	360	0
Sediment	0.654	1.44e+003	0

	Fugacity (atm)	Reaction (kg/hr)	Advection (kg/hr)	Reaction (percent)	Advection (percent)
Air	1.92e-022	0.00124	0.000284	0.000124	2.84e-005
Water	3.51e-015	657	341	65.7	34.1
Soil	9.22e-021	0.000746	0	7.46e-005	0
Sediment	2.1e-015	1.08	0.045	0.108	0.0045

Persistence Time: 344 hr  
 Reaction Time: 522 hr  
 Advection Time: 1.01e+003 hr  
 Percent Reacted: 65.8  
 Percent Advected: 34.2

**Half-Lives (hr), (based upon Biowin (Ultimate) and Aopwin):**

Air: 15.88  
 Water: 360  
 Soil: 360  
 Sediment: 1440  
 Biowin estimate: 3.149 (weeks )

**Advection Times (hr):**

Air: 100  
 Water: 1000  
 Sediment: 5e+004

**Conclusion** Indirect photolysis in air results in a half-life of 7.9 hours for the test substance.  
 Discharge into water results in the following distribution:  
 water/air/soil/sediment = 99.3/0/0/0.65%

**Rev. note** -  
**Klimisch** 4  
**criterion**

**Title** Determination of 'ready' biodegradability: carbon dioxide (CO<sub>2</sub>) evolution test (modified Sturm test) with Lathanol LAL powder.  
**Date of report** June 17, 2003.  
**GLP** Yes.  
**Reference** 11.  
**Test substance** CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.  
**Guideline** OECD 301B

**Procedure**

A stock solution of 1.00 g/L Lathanol LAL powder was prepared using ultrasonication. The stock was a light glassy solution. Since calculation of the theoretical TOC value was not possible, the TOC concentration of the stock was measured and determined to be 361.5 mg/L. The theoretical CO<sub>2</sub> production based on the TOC was calculated to be 1.33 mg CO<sub>2</sub>/ml stock solution.

Duplicate test mixtures were incubated with activated sludge in 2 L brown-coloured glass bottles with three serial CO<sub>2</sub>-absorbers ((Ba(OH)<sub>2</sub>) each and at a temperature of 21.4-23.5 °C for 28 days. Test mixtures contained test substance (33 mg/L) and filtrate of non-adapted inoculum (10 ml/L mineral medium) in mineral medium as prescribed in OECD 301B. The following controls were included:

- Inoculum blank: control without test substance but with inoculum (2 flasks).
- Positive control: reference substance (sodium acetate; 40 mg/L) with inoculum (1 flask).
- Toxicity control: Lathanol LAL powder (33 mg/L), sodium acetate (40 mg/L) and inoculum (1 flask).

Evolution of carbon dioxide was determined on day 0, 2, 5, 7, 9, 14, 14, 19, 23, 27 and 29 by titrating the remaining barium hydroxide with 0.05 M hydrogen chloride.

**Results**

Day	% degradation			
	TS with inoculum			Sodium acetate
	A (33 mg/L)	B (33 mg/L)	Mean	
2	0	0	0	6
5	5	20	12	40
9	18	33	26	65
19	42	51	47	85
23	45	56	50	88
29	51	62	56	94

**Conclusions**

Lathanol LAL powder is not readily biodegradable under the above test conditions.

**Rev. note**

1. The test substance was not inhibitory on microbial activity.

**Klimisch**

1

**criterium****Title**

Determination of ready biodegradability closed bottle test (Weston study 91-001),.

**Date of report**

October 20, 1992.

**GLP**

Yes.

**Reference**

3.

**Test**

Lathanol LAL slurry (a.i. sodium lauryl sulfoacetate (CAS 1847-58-1)), purity 15.1% (carbon content 7.8% (w/w) in this formulation)

**substance****Guideline**

OECD 301 D

**Procedure**

Duplicate test mixtures (7 flasks) were incubated in 300 mL glass BOD bottles at 20 +/- 0.2 °C for 28 days. Test mixtures (in completely filled flasks) contained test substance (2 mg/L or 5 mg/L), filtrate of (non-adapted) effluent from duplicate semi-continuous activated sludge units (40 µL) and mineral medium essentially as prescribed in OECD 301 D. The following controls were included:

- Inoculum blank: control without test substance but with inoculum (7 flasks).
- Positive control: reference substance (sodium benzoate; 2 mg/L) with inoculum (7 flasks).
- Complete blank: control without test substance and without inoculum (7 flasks).

Dissolved oxygen was determined on day 0, 5, 15 and 28. Degradation was calculated as BOD/COD. On day 0 single flasks were analysed, on the other time points duplicate flasks were analysed. Only BOD<sub>5</sub> was determined for glucose/glutamic acid control.

**Results**

Day	% degradation <sup>1</sup>		
	TS with inoculum <sup>1</sup>		Sodium benzoate <sup>1</sup>
	2 mg/L	5 mg/L	
5	31.6	30.9	68.4
15	43.2	34.9	74.7
28	65.9	>38.4 <sup>2</sup>	>100 <sup>2</sup>

<sup>1</sup> mean of two replicates

<sup>2</sup> dissolved oxygen value was below detection limit, therefore ">" value was reported

**Conclusions** Some components of the formulation are biodegradable.  
**Rev. note** 1. Composition was not specified. Oxygen consumption observed may (partly) represent biodegradation of additives.  
 2. No abiotic control was included. Since the report does not indicate that the test was performed in the dark, photodegradation cannot be excluded.  
**Klimisch criterium** 3 Degradation may be related to other components (note 1).

### Aquatic Toxicity

**Title** Acute toxicity study in *Daphnia magna* with Lathanol LAL powder (semi-static).  
**Date of report** 18 December, 2003.  
**GLP** Yes.  
**Reference** 13.  
**Test substance** CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.  
**Test method** OECD 202.  
**Test system** **Species** *Daphnia magna*, <24 h old.  
**No. of daphnids** 5/replicate, 4 replicates/treatment.  
**Concentrations** Nominal: 1.0, 2.2, 4.6, 10, 22 and 46 mg/L (no vehicle; prepared from stock solution 46 mg/L); blank control.  
**Test conditions** Semi-static without aeration; in 100 mL glass beakers containing 80 mL of medium (hardness 201 mg/L as CaCO<sub>3</sub>), 16 h light, no feeding.  
**Exposure time** 48 hours.  
**Analyses** LC-MS. Samples taken at 0 and 24 h from freshly prepared solutions, and at 24 and 48 h from 24 h-old solutions.  
**Phys. meas.** pH and dissolved oxygen: at 0, 24 and 48 h for all concentrations and control; pH = 7.8-7.9 and dissolved oxygen = 8.8-9.3 mg/L.  
Temperature: continuously; 20-21 °C  
 Physical parameters remained within the required ranges during the test.  
**Observations** Immobility at 24 and 48 h.  
**Stat. method** Probit analysis.  
**Results** **Ref. product** A test with the reference substance K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub> was performed in August 2003. The 48 h-EC<sub>50</sub> of K<sub>2</sub>Cr<sub>2</sub>O<sub>7</sub> was 0.75 mg/L.  
**Analysis** Measured concentrations were within 82-99% of the nominal concentrations.

#### Biological results

Parameter	Time [h]	Nominal concentration [mg/L]					
		1.0	2.2	4.6	10	22	46
Immobility [%]	24	0	0	0	40	85	100
	48	0	0	0	80	100	100

**Conclusions** 48-h EC<sub>50</sub> = 7.9 mg/L (equivalent to 5.9 mg/L based on a.i.).  
**Rev. note** 1. The two highest test concentrations still contained a very thin layer of foam. All final test solutions were clear and colourless.  
**Klimisch criterium** 1

**Title** Fresh water algal growth inhibition test with Lathanol LAL powder.  
**Date of report** 18 December, 2003.  
**GLP** Yes.  
**Reference** 14.  
**Test substance** CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.  
**Guideline** OECD 201.  
**Test system** **Species** *Selenastrum capricornutum*, strain: NIVA CHL 1.  
**Initial cell conc.** 1\*10<sup>4</sup> cells/mL.  
**No. of replicates** 3 per treatment; 6 for blank control; 1 replicate of each test concentration without algae; 1 extra replicate of each test concentration and blank control for sampling purposes.  
**Concentrations** Nominal 1.0, 2.2, 4.6, 10, 22, 46 and 100 mg/L, blank control.

**Test conditions** 72-h static test in 100 ml glass vessels containing medium (in accordance with OECD 201) with continuous illumination (ca. 4900-6400 lux).

**Analysis** LC-MS. Samples were taken at 0, 24 and 72 h.

**Phys. meas.** pH: at 0 and 72 h; 7.8-9.0; in the blank control an increase of 1.5 was observed which correlated with a high rate of algal growth (7.9-9.4)

**Observations** Temperature: continuously; 23.0 – 24.1°C.  
Cell density at 0, 24, 48 and 72 h by spectrophotometry or microscope using a counting chamber.

**Stat. method** ANOVA, Bonferroni t-test, Tukey test and Williams' test.

**Results** For biological data see table below. Growth factor control = 95.

*Biological results*

Parameter	Time [h]	Measured concentration [mg/L]							
		0	0.36	0.86	1.7	3.4	7.2	14	31
Mean cell density [x10 <sup>4</sup> cells/ml]	0	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
	24	3.1	2.8	2.6	2.1	1.4	1.3	2.2	1.3
	48	24.3	20.3	19.4	15.0	8.1	1.9	2.0	1.3
	72	95.5	80.4	81.0	62.9	33.6	6.0	6.1	1.3
Inhibition [%] – AUC	72-h		16.3	17.5	36.7	67.2	94.9	93.5	99.1
Inhibition [%] – growth rate	72-h		4.0	3.7	9.2	24.2	60.7	60.4	95.9

**Conclusions** 72 h-E<sub>b</sub>C<sub>50</sub> = 1.9 mg/L.  
72 h-E<sub>r</sub>C<sub>50</sub> = 6.8 mg/L.  
NOEC<sub>r</sub> = 0.86 mg/L.

**Rev. note** 1. The nominal 72 h-E<sub>r</sub>C<sub>50</sub> of potassium dichromate was 0.89 mg/L.  
2. Initial test solutions were all clear and colourless. Concentrations were not stable, especially over the last 48 hours. The concentrations in the vessels without algae decreased to the same extent. This is explained by possible biodegradation, since the test solutions became turbid during exposure, which may indicate bacterial growth.

**Reliability** 1.

**Title** EPISUITE v.3.10

**Date of report** -

**GLP** Not applicable.

**Reference** 18.

**Test substance** CAS 1847-58-1, acetic acid, sulfo-, 1-dodecyl ester, sodium salt.

**Guideline** Not applicable.

**Remarks**

ECOSAR Class	Organism	Duration	End Point	mg/L (ppm)
=====	=====	=====	=====	=====
Esters :	Fish	96-hr	LC50	22.180
Esters :	Daphnid	48-hr	LC50	65.836
Esters :	Green Algae	96-hr	EC50	1.809

**Rev. note** Calculated.

**Klimisch criterium** 4

## Mammalian Toxicity

### Acute Toxicity

**Title** Acute oral toxicity study (TM study 97-119-3A).

**Date of report** October 31, 1997.

**GLP** Yes.

**Reference** 1.

**Test substance** CAS: 1847-58-1, sodium lauryl sulfoacetate, purity 64-85%; impurities 5-18% sodium sulphate and 10-18% sodium chloride.

**Guideline** OECD 401.  
**Stat. method** Not applicable.  
**Test system** **Species** Rat (Sprague-Dawley), weight males 219-223 g, weight females 200-204 g; age 6-10 weeks; source: Harlan Sprague-Dawley, Indianapolis  
**No. of animals** 5/sex/treatment.  
**Dosage** Single oral administration by gavage of 2000 mg/kg bw (vehicle distilled water, concentration 33% w/v); no controls; feeding *ad libitum* (food was withheld overnight prior to dosing).  
**Observations** Mortality and clinical signs several times on day 1 and daily thereafter until day 14.  
 Bodyweight at study initiation, on days 7 and 14 and at death  
 Necropsy on day 14.

**Results**

Effect/Dose [mg/kg bw]		2000	
Sex	Day	M	F
Mortality (day)	1-14	1 (2)	1 (2)
BW		- (animal that died)	- (animal that died)
Clinical signs <sup>(A)</sup>	1-14	+	+
Necropsy <sup>(B)</sup>	14	+	+

(A) Clinical observations included loose stool, hypoactivity and prostration (one animal) on day 1.

(B) Only in the animals that died stomach and intestines distended with gas and fluid were seen. The female also displayed a small intestine red in colour.

**Conclusions** Oral LD<sub>50</sub> > 2000 mg/kg bw.

**Klimisch criterium** 1

**Title** Acute dermal toxicity (TM study 97-119-4),  
**Date of report** September 29, 1997  
**GLP** Yes  
**Reference** 2  
**Test substance** CAS: 1847-58-1, Sodium Lauryl Sulfoacetate, purity 64 – 85%; impurities 5-18% sodium sulphate and 10-18% sodium chloride.  
**Guideline** OECD 402  
**Stat. method** Not applicable  
**Test system** **Species** Rabbit (New Zealand White), weight 2.0-2.4 kg, age 8-12 weeks  
**No. of animals** 5/sex/treatment.  
**Dosage** Single administration of 2000 mg/kg bw (substance was slightly moistened before administration); area of application ca. 10% of total body surface (under occlusion); contact period of 24 hours; no controls;  
**Observations** Mortality and clinical signs several times on day 1 and daily thereafter until day 14.  
 Body weight prior to dosing, on days 7 and 14, and at death.  
 Necropsy on day 14.

**Results**

Effect/Dose [mg/kg bw]		2000	
Sex	Day	M	F
Mortality (day)	1-14	3 (4 or 5)	1(4)
Clinical signs <sup>(A)</sup>	1-14	+	+
Necropsy <sup>(B)</sup>	14	+	-

(A) Clinical observations included erythema (until day 7-8), oedema (until day 9-11), eschar&coriaceousness (until day 11-14) and formation of scar tissue. Three males exhibited chemical burns until day 3-4 (death).

(B) Findings consisted of severe tissue damage & necrosis of the skin at the application site in all rats that died, a stomach devoid of contents in two males that died and scar tissue at the application site in some surviving animals.

**Conclusions** Dermal LD<sub>50</sub> > 2000 mg/kg bw.

**Klimisch criterium** 1



**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.  
**Date of report** 1987.  
**GLP** No.  
**Reference** 9.  
**Test substance** Bath additive.  
**Guideline** Not indicated.  
**Remarks** Groups of 10 female Harlan Wistar rats (115-135 g) were given single oral doses (5-14 g bath additive/kg) of a bath additive (containing 50% sodium lauryl sulfoacetate) as a 35% aqueous solution. Leg weakness, obtunded righting reflex, ataxia, diuresis and diarrhea were observed. Most deaths occurred 4-24 h after treatment.  
**Conclusion** LD<sub>50</sub> = 5.75 g/kg bath additive (= 0.7 g/kg sodium lauryl sulfoacetate). Recalculated by the reviewer as 5.75 x 0.5 x 0.35 = 1.0 g/kg sodium lauryl sulfoacetate.  
**Rev. note** The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.  
**Klimisch criterium** 3

#### *Skin/eye irritation*

**Title** OECD guideline 404 primary dermal irritation/corrosion study (TM 97-119-2).  
**Date of report** September 29, 1997.  
**GLP** Yes.  
**Reference** 15.  
**Test substance** Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.  
**Guideline** OECD 404.  
**Test system** **Species** Rabbit (New Zealand White), weight 1850-2320 g.  
**No. of animals** 6 males.  
**Dosage** Application of 0.5 g test substance, moistened with distilled water, on the clipped skin under semi-occlusion for 4 hours.  
**Observations** Skin observations at ½, 24, 48 and 72 h and at 7 and 14 days after removal of the dressing.

#### Results

Animal	1		2		3		4		5		6	
Time	E	O	E	O	E	O	E	O	E	O	E	O
½ h	1	0	1	1	1	2	1	2	1	2	1	2
24 h	1	0	0	0	1	1	2	1	2	1	2	2
48 h	1	0	0	0	2	0	2	0	2	0	3	1
72 h	1	0	0	0	2	0	2	0	2	0	3	1
7 days	0	0	0	0	0	0	0	0	0	0	1	0
14 days	0	0	0	0	0	0	0	0	0	0	0	0

E=erythema

O=oedema

#### Conclusions

Moderately irritating.

#### Klimisch

1

#### criterium

**Title** DOT test for corrosivity.  
**Date of report** May 31, 1977.  
**GLP** No.  
**Reference** 16.  
**Test substance** Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.  
**Guideline** Not specified.  
**Test system** **Species** Rabbit.  
**No. of animals** 6 males.  
**Dosage** Application of 0.5 ml test substance on the clipped skin under occlusion for 4 hours.  
**Observations** Skin observations at 0, 24, and 72 after removal of the dressing.

#### Results

Animal	1		2		3		4		5		6	
Time	E	O	E	O	E	O	E	O	E	O	E	O
0 h	1	1	1	0	1	1	1	1	1	1	1	1
24 h	1	0	1	0	1	0	0	0	1	0	0	0
72h	0	0	0	0	0	0	0	0	0	0	0	0

E=erythema

O=oedema

**Rev. note** 1. The scoring used is not known to the reviewer; the appendix was not included.

**Klimisch criterium** 4 The information given is limited to the above mentioned.

**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.

**Date of report** 1987.

**GLP** No.

**Reference** 9.

**Test substance** CAS: 1847-58-1, Sodium Lauryl Sulfoacetate.

**Guideline** Not indicated.

**Remarks** Undiluted sodium lauryl sulfoacetate (0.5 g) moistened with 0.9% saline was applied to the skin of 6 New Zealand rabbits for 24 hours (semi-occlusion). Test sites were scored at 30 min and 24 hours after patch removal. The mean PII was 2.7. One animal had areas of possible necrosis within the test site at 24 hours.

**Rev. note** The information given was limited to the above mentioned. Worst case exposure (24 h).

**Klimisch criterium** 4

**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.

**Date of report** 1987.

**GLP** No.

**Reference** 9.

**Test substance** Bath additive.

**Guideline** Not indicated.

**Remarks** Undiluted bath additive (powder; 500 mg) containing 35% of sodium lauryl sulfoacetate (175 mg) and a 1% solution of the bath additive were applied to the skin of 3 rabbits for 4 days. No irritation was observed at the sites treated with the powdered bath product. All sites treated with 1% solution had slight erythema on day 2 but were normal on day 7.

**Rev. note** The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.

**Klimisch criterium** 3

**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.

**Date of report** 1987.

**GLP** No.

**Reference** 9.

**Test substance** Bath additive.

**Guideline** Not indicated.

**Remarks** Undiluted bath additive (powder; 500 mg) containing 35% of sodium lauryl sulfoacetate (175 mg) and a 1% solution of the bath additive were applied to separate sites on the skin of 3 rabbits for 4 days. No irritation was observed at the sites treated with the powdered bath product. All sites treated with 1% solution had slight erythema on day 2 but were normal at day 7.

**Rev. note** The information given was limited to the above mentioned. The other components of the bath additive are not known and thus the toxicity seen might be attributable to another component.

**Klimisch criterium** 3

**Title** OECD guideline 405 acute eye irritation/corrosion study (TM 97-119-1).  
**Date of report** October 2, 1997.  
**GLP** Yes.  
**Reference** 17.  
**Test substance** Lathanol LAL, purity 64-85%; impurities: 5-18% sodium sulfate, 10-18% sodium chloride.  
**Guideline** OECD 405.  
**Test system** **Species** Rabbit (New Zealand White), weight 2010-2300 g.  
**No. of animals** 6 females.  
**Dosage** Instillation of 87-90 mg test substance (0.1 ml).  
**Observations** At 1, 24, 48 and 72 h and at 7, 14 and 21 days after removal of the dressing.  
 From 24 hours onwards also fluorescein and UV-light examination was used.

**Results**

Animal	1				2				3				4				5				6			
Time	C	I	Conj <sup>(A)</sup>		C	I	Conj <sup>(A)</sup>		C	I	Conj		C	I	Conj <sup>(A)</sup>		C	I	Conj <sup>(A)</sup>		C	I	Conj <sup>(A)</sup>	
			R	Ch			R	Ch			R	Ch			R	Ch			R	Ch			R	Ch
1 h	-	1	2	2	-	1	2	3	-	0	2	2	-	1	2	3	-	0	2	3	-	1	2	2
24 h	1	1	2	2	1	1	2	2	1	1	2	1	1	1	2	2	1	1	2	2	1	1	2	2
48 h	1	1	2	2	1	1	2	2	1	1	2	1	1	0	2	2	1	0	2	2	1	0	2	1
72 h	1	1	2	2	1	1	2	2	1	0	2	1	1	0	2	2	1	0	1	1	1	0	1	1
7 days	1	1	1	1	1	1	2	2	1	0	1	1	1	0	2	2	1	0	1	1	0	0	1	1
14 days	2	1	1	1	2	1	2	2	0	0	1	0	0	0	1	0	0	0	1	0	0	0	0	0
21 days	2	0	1	0	3	1	2	1	0	0	0	0	0	0	1	0	0	0	0	0	0	0	0	0

C=corneal opacity I=Iris Conj=conjunctiva Red=redness Ch=chemosis.

(A) Severe discharge was observed.

**Conclusions** Moderately irritating.**Klimisch criterium** 1**Title** Final report on the safety assessment of sodium lauryl sulfoacetate.**Date of report** 1987.**GLP** No.**Reference** 9.**Test substance** Bath additive/milk.**Guideline** Not indicated.

**Remarks** One eye of six rabbits was treated with 0.1 ml 1% solution of bath additive containing 35% sodium lauryl sulfoacetate and observed for 4-7 days. Slight conjunctival redness was observed 1 h after treatment and had dissipated by 48 h. The cornea and iris appeared normal.

One eye of three female New Zealand rabbits was treated with a 10% aqueous solution of a milk bath containing 30% sodium lauryl sulfoacetate. All rabbits had minimal conjunctival irritation at 1 and 24 h and no irritation at 48 h.

**Conclusion** A 0.35% and 3% solution of sodium lauryl sulfoacetate are not irritating to the eye.

**Rev. note** The information given was limited to the above mentioned. The other components of the bath additive/milk bath are not known and thus the toxicity seen might be attributable to another component.

**Klimisch criterium** 3**Mutagenicity****Title** Mutagenicity evaluation of 2800-00, Lot 28M024 in the Ames Salmonella/ Microsome plate test.**Date of report** September 20, 1978.**GLP** No.**Reference** 6.

**Test substance** 2800-00, Lot 28M024, purity not indicated.  
**Guideline** Not indicated.  
**Test system** **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4 (*Saccharomyces cerevisiae*).  
**Initial bacteria conc.** Ca.  $10^8$  cells from an overnight culture.  
**Metabolic activation** Liver S9 mix (Aroclor 1254-induced).  
**Test concentrations** 1, 10, 100, 500 and 1000 µg /plate.  
**Controls** Negative: solvent (DMSO).  
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.  
**Test type** Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.  
**No. of replicates** 1.  
**Criteria for evaluating results** The result was considered positive, if a positive dose response was observed over three concentrations.

**Results**

Tester strain	Test result <sup>(A)</sup>	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.  
 Cytotoxicity was observed at 1000 µg/plate.

**Conclusion** Not mutagenic.

**Rev. note** 1. According to handwritten text on the front page of the report, substance 2800-00, Lot 28M024 corresponds to sodium lauryl sulfoacetate, 3% in shampoo.  
 2. For each test concentration only single experiments were performed.  
**Klimisch criterium** 2 Single experiments (see note 2); non GLP.

**Title** Mutagenicity evaluation of 2300-00, Lot 23N056 in the Ames Salmonella/microsome plate test.

**Date of report** September 21, 1978.

**GLP** No.

**Reference** 7.

**Test substance** 2300-00, Lot 23N056, purity not indicated.

**Guideline** Not indicated.

**Test system** **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4 (*Saccharomyces cerevisiae*).  
**Initial bacteria conc.** Ca.  $10^8$  cells from an overnight culture.  
**Metabolic activation** Liver S9 mix (Aroclor 1254-induced).  
**Test concentrations** 1, 10, 100, 500 and 1000 µg /plate.  
**Controls** Negative: solvent (water).  
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.  
**Test type** Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.  
**No. of replicates** 1.  
**Criteria for evaluating results** The result was considered positive, if a positive dose response was observed over three concentrations.

**Results**

Tester strain	Test result <sup>(A)</sup>	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.

Slight cytotoxicity was observed at 1000 µg/plate.

**Conclusion** Not mutagenic.

**Rev. note** 3. According to handwritten text on the front page of the report, substance 2300-00, Lot 23N056 corresponds to sodium lauryl sulfoacetate, 23% in a cleansing bar.

4. For each test concentration only single experiments were performed. A repeat test was conducted for TA1535 and TA1537 and the result was also negative.

**Klimisch criterium** 2 Single experiments (see note 2); non GLP.

**Title** Mutagenicity evaluation of 3000-00, Lot 30M366 in the Ames Salmonella/microsome plate test.

**Date of report** September 13, 1978.

**GLP** No.

**Reference** 8.

**Test substance** 3000-00, Lot 30M366, purity not indicated.

**Guideline** Not indicated.

**Test system** **Bacterial strains** TA98, TA100, TA1535, TA1537, TA1538 and D4(Saccharomyces cerevisiae).

**Initial bacteria conc.** Ca. 10<sup>8</sup> cells from an overnight culture.

**Metabolic activation** Liver S9 mix (Aroclor 1254-induced).

**Test concentrations** 1, 10, 100, 500 and 1000 µg /plate.

**Controls** Negative: solvent (water).  
Positive: N-methyl,N-nitro,N-nitrosoguanidine (TA1535, TA100, D4), 9-aminoacridine (TA1537), 2-nitrofluorene (TA98 and TA1538) all without S9; 2-anthramine for all strains with S9.

**Test type** Plate incorporation; incubation for 48 h at 37 °C. D4-yeast plates were incubated at 30 °C for 3-5 days.

**No. of replicates** 1.

**Criteria for evaluating results** The result was considered positive, if a positive dose response was observed over three concentrations.

**Results**

Tester strain	Test result <sup>(A)</sup>	
	Without activation	With activation
TA98	-	-
TA100	-	-
TA1535	-	-
TA1537	-	-
TA1538	-	-
D4	-	-

+/- : positive/negative result; positive controls gave expected responses.

Cytotoxicity was observed at 1000 µg/plate.

**Conclusion** Not mutagenic.

**Rev. note** 5. According to handwritten text on the front page of the report, substance 3000-00, Lot 30M366 corresponds to sodium lauryl sulfoacetate, 19% in a cleansing bar.

6. For each test concentration only single experiments were performed.

**Klimisch criterium** 2 Single experiments (see note 2); non GLP.

**Title** Evaluation of the ability of Lathanol LAL powder to induce chromosome aberrations in cultured peripheral human lymphocytes.

**Date of report** July 22, 2003.

**GLP** Yes.

**Reference** 12.

**Test substance** CAS 1847-58-1, Lathanol LAL powder, purity 74.26%.

**Guideline** OECD 473.

**Stat. method** Chi-square test.

**Test system** **Cell line** Human lymphocytes.  
**Metabolic activation** Rat S9 mix (Aroclor 1254-induced).  
**Test concentrations** 50 - 500 µg/ml (based on cytotoxicity).  
**Controls** Negative: vehicle control (DMSO).  
Positive: mitomycin-C (-S9), cyclophosphamide (+S9).  
**Procedure** -S9: 3 h exposure + 24 h fixation.  
24 h exposure + 24 h fixation.  
48 h exposure + 48 h fixation.  
+S9: 3 h exposure + 24 h fixation.  
3 h exposure + 48 h fixation.  
Colchicine was added for the last 3 hours.

**Results**

Exposure/fixation (h)	Metabolic activation	Doses evaluated [µg/ml]	Aberrations [%]	Test result <sup>(A)</sup>
3/24	Without	0, 100, 300, 500	3, 7, 4, 5	-
3/24	With	0, 100, 300, 500	2, 3, 6, 7	-
3/48	With	0, 300, 400, 500, 600	0, 0, 3, 5, 9	+/-
24/24	Without	0, 100, 125, 200	2, 5, 0, 1	-
48/48	Without	0, 56, 100, 130	1, 4, 1, 5	-

(A)+/- : positive/negative result; positive controls gave expected responses.

Cytotoxicity was observed at ≥200 without metabolic activation and ≥500 µg/ml with metabolic activation.

**Conclusion** Not clastogenic.

**Rev. note** All values remained within historical control values. The statistically significant increase in the number of cells with chromosome aberrations at 600 µg/ml was ascribed to the strongly cytotoxic effect of this concentration (MI 36%).

**Reliability** 1.

*Repeated Dose Toxicity*

**Title** 28 day oral range finding study in the rat.

**Date of report** August 1985.

**GLP** Yes.

**Reference** 4.

**Test substance** CAS 1847-58-1 (sodium lauryl sulfoacetate), purity 73.80%; impurities: 13.09% sodium chloride, 11.39% sodium sulfate, 1.95% free oil and 0.28% water.

**Guideline** Not indicated.

**Stat. method** Student's t-test.

**Test system** **Species** CD rat.  
**Source** Charles River UK.  
**Bodyweight** Males 123-149 g g, females 114-142 g.  
**No. of animals** 5/sex/treatment.  
**Dosage** 0, 50, 200 and 800 mg/kg/day by gavage (dosing volume 10 ml/kg/day).  
**Vehicle** Distilled water.  
**Exposure period** 28 days.

**Investigations** **General** Clinical signs, mortality (daily), food consumption (group mean weekly), bodyweight (daily).  
**Clinical pathology** Haematology: haematocrit, haemoglobin, erythrocyte count, mean cell volume, mean cell haemoglobin concentration and total leucocyte count.  
Biochemistry: blood urea nitrogen, glucose, alkaline phosphatase, glutamate pyruvate transaminase, glutamate oxaloacetate

**Necropsy** transaminase and total protein.  
Gross examination, macroscopy of cranial, thoracic and visceral cavities, organ weights (brain, kidneys, liver).

**Analysis** Concentration analysis on day 1.

**Results**

Dose	0 mg/kg		50 mg/kg		200 mg/kg		800 mg/kg		Dose related	
Sex	M	F	M	F	M	F	M	F	M	F
Mortality	No deaths occurred									
Clinical Signs (A)						+	+	+		
Body weight (gain)										
Food consumption						d		d		
Haematology	No changes of toxicological significance.									
Clinical chemistry	No changes of toxicological significance.									
Necropsy										
Macroscopy (B)							+			
Liver weight							i <sup>a,r</sup>			
Kidney weight								ic <sup>r</sup>		
Brain weight								ic <sup>r</sup>		

Where i=increase; d=decrease; ic=significant increase; dc=significant decrease; <sup>a</sup>=absolute; <sup>r</sup>=relative.

(A) Poor coat condition; was already present in all animals before treatment but had disappeared by day 11 except for females at 800 mg/kg. Males at 800 mg/kg and females at 200 mg/kg showed the condition again from day 22 and 15 resp. Post dose salivation in all animals at 800 mg/kg.

(B) Raised black foci on the non glandular mucose of the stomach in one male.

**Actual concentrations** Concentrations as measured were 98-108% of nominal concentrations.

**Conclusions** NOAEL = 200 mg/kg/day and LOAEL = 800 mg/kg/day based on <10% effect on body weight.

**Rev. note**

1. No histological examinations were performed.
2. Only limited biochemical parameters were investigated.
3. Only a limited number of organs were weighed.

**Klimisch criterium** 2.

**Title** 90 day oral toxicity study in the rat.

**Date of report** March 1986.

**GLP** Yes.

**Reference** 5.

**Test substance** CAS 1847-58-1 (sodium lauryl sulfoacetate), purity 73.80%; impurities: 13.09% sodium chloride, 11.39% sodium sulfate, 1.95% free oil and 0.28% water.

**Guideline** Not indicated.

**Stat. method** ANOVA, Student's t-test.

**Test system**

**Species** Rat, CD (SD) BR strain.

**Source** Charles River UK.

**Bodyweight** Males 114-153 g g, females 106-135 g.

**No. of animals** 20/sex/treatment; satellite group of 10/sex for to provide pre-exposure clinical pathology.

**Dosage** 0, 75, 250 and 750 mg/k/day by gavage (dosing volume 10 ml/kg).

**Vehicle** Distilled water.

**Exposure period** 91 days.

**Investigations**

**General** Clinical signs and mortality (daily), food consumption (group mean weekly), bodyweight (daily), ophthalmoscopy (before study initiation in all animals and after 4 and 12 weeks of treatment in high dose and control animals).

**Clinical pathology** Haematology (pre-exposure, wk 4 and wk 12): haematocrit, haemoglobin, erythrocyte count, mean cell volume, mean cell haemoglobin concentration, total and differential leucocyte count prothrombin time and partial thromboplastin time.

Biochemistry (pre-exposure, wk 4 and wk 12) blood urea nitrogen, glucose, alkaline phosphatase, glutamate pyruvate transaminase, glutamate oxaloacetate transaminase, total protein and

albumin/globulin, sodium and potassium.

Urinalysis (pre-exposure, wk 4 and wk 12): samples were collected overnight to measure following parameters: volume, appearance and colour, specific gravity, pH, glucose, protein, ketones, bilirubin, blood pigments and deposit.

### Necropsy

Gross examination;

Macroscopy of cranial, thoracic and visceral cavities;

Organ weights of brain, kidneys, liver, adrenals, heart, lungs, ovaries, pituitary, spleen, testes, thyroids and uterus;

Microscopy of following organs for animals in the high dose and control group: adrenals, aortic arch, brain, caecum, cervical lymph nodes, colon, duodenum, epididymes, eyes, heart, ileum, jejunum, kidneys, liver, lungs, caudal and cranial mammary gland, mesenteric lymph nodes, optic nerve, ovaries, pancreas, pituitary, prostate, spleen, stomach, testes, thymus, thyroids, urinary bladder and uterus. Stomachs of middle and low dose animals were also examined.

**Analysis** Concentration analysis on day 1 by comparing absorbances with those of standard solutions.

### Results

Dose	0 mg/kg		75 mg/kg		250 mg/kg		750 mg/kg		Dose related	
Sex	M	F	M	F	M	F	M	F	M	F
Mortality	No test substance related deaths occurred*									
Clinical Signs (A)					+	+	+	+		
Body weight gain	No treatment related changes.									
Food consumption	No treatment related changes.									
Ophthalmoscopy	No treatment related changes.									
Haematology										
WBC, wk 4 (wk 12)**							dc (d)			
Clinical chemistry	No changes of toxicological significance.									
BUN, wk 4 (wk12)**				(ic)		lc (ic)		lc (ic)		
Urinalysis										
Urinary volume (B)								i		
Specific gravity								d		
Necropsy	No test substance related abnormalities.									
Macroscopy										
Liver weight								ic <sup>a,r</sup>		
Microscopy (C)					+	+	+	+	x	x

Where i=increase; d=decrease; ic=significant increase; dc=significant decrease; <sup>a</sup>=absolute; <sup>r</sup>=relative.

\*One control female died during blood sampling.

\*\*The changes were not of toxicological significance.

(C) Post dose salivation from week 3 (750 mg/kg) of week 8 (250 mg/kg) on.

(D) Increased volume after both 4 and 12 weeks, reduced specific gravity after 12 weeks.

(E) Changes were restricted to the stomach and consisted of hyperplasia of the non-glandular squamous epithelium, with associated focal epithelial erosion and varying degrees of gastritis in some rats. In females at high dose, epithelial whorls were seen in the thyroid.

**Actual concentrations** Concentrations as measured were 99% of nominal concentrations.

**Conclusions** NOAEL = 75 mg/kg/day and LOAEL = 250 mg/kg/day, as based on histological changes in stomach mucosa in both sexes.

**Rev. note** Study is in accordance with the old OECD guideline 408 (1981). The new guideline requires a more extensive biochemical and histological examination, recording of more organ weights and measurement of sensory reactivity.

**Klimisch criterium** 1